DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0437 6 JAN 12 P2:35

Date: DEC 28 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Geranti Bio-Ge Yeast, *Saccharomyces cerevisiae*

Firm: Gary J. Burin, Ph.D., on behalf of Geranti USA, Inc.

Date Received by FDA: October 3, 2005

90-Day Date: January 1, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

1995-0316

RPT 308

DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

DEC 14 2005

Gary J. Burin, Ph.D., DABT
Technology Sciences Group, Inc.
1101 17th Street, N.W., Suite 500
Washington D.C., 20036

Dear Dr. Burin:

This is to inform you that the notification, dated September 20, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) on behalf of your client Mr. Tsang-Uk Sohn of Geranti USA, Inc. was filed by the Food and Drug Administration (FDA) on October 3, 2005. Your notification concerns the substance Geranti Bio-Ge Yeast that you intend to market as a new dietary ingredient.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification concerning "Geranti Bio-Ge Yeast" does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your notification provided a chronic oral toxicity study in Beagle dogs from the Kang-Won National University, Korea. According to the regulations, if any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The translation of the study report provided to support the safety of the new dietary ingredient, "Geranti Bio-Ge Yeast," does not provide an accurate translation that is interpretable in English. In addition, the report does not contain any of the histopathology data that is mentioned in the methods section f the report. As a result FDA cannot review this study.

If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (http://www.cfsan.fda.gov/~lrd/cfr190-6.html), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of October 3, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

GERANTI BIO-GE YEAST

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October 3, 2005

Vicky Lutwak
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Room 4D011
5100 Paint Branch Parkway
College Park, MD 20740

Re: Pre-Market Notification for *Geranti Bio-Ge* Yeast as New Dietary Ingredient.

Dear Ms. Lutwak:

Attached please find three copies of the study entitled "Chronic Oral Toxicity Study with Geranti Dry Yeast-G (Geranti Bio-Ge Yeast) in Beagle Dogs". This document replaces the version of the study in September 30th submission. That version was from a scientific journal and most of the article was in the Korean language. The attached version summarizes the same study as the Korean publication.

I am also attaching three copies of the article entitled "A Study on Preparation and Binding Properties of Germanium-fortified Yeast" by Lee et al. Please amend our submission to include this relevant publication. The publication shows that the Germanium in Bio-Ge Yeast is not dissociated in simulated gastric juice.

This submission is made on behalf of Mr. Tsang-Uk Sohn of Geranti USA, Inc. of Los Angeles California.

Best regards,

Gary J. Burin, Ph.D., DABT